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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,449	01/09/2006	Bernd Schwenzer	101215-189	1690

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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/537,449	SCHWENZER ET AL.	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *12,17,18 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11, 13-16, 19-21, 23-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, drawn to a polynucleotide directed towards a gene if a catalytic subunit of human telomerase, wherein the polynucleotide is an antisense oligonucleotide.

Group II, claim(s) 1-11, drawn to a polynucleotide directed towards a gene if a catalytic subunit of human telomerase, wherein the polynucleotide is a DNAzyme.

Group III, claim(s) 1-11, drawn to a polynucleotide directed towards a gene if a catalytic subunit of human telomerase, wherein the polynucleotide is a peptide nucleic acid.

Group IV, claim(s) 1-11, drawn to a polynucleotide directed towards a gene if a catalytic subunit of human telomerase, wherein the polynucleotide is a ribozyme.

Group V, claim(s) 1-11, drawn to a polynucleotide directed towards a gene if a catalytic subunit of human telomerase, wherein the polynucleotide is an siRNA.

If any of groups I-V is elected, applicants are further required to elect two target sequence regions from 2183-2205, 2206-2225, 2315-2334, 2317-2336, 2324-2346, 2331-2350, and 2333-2352 as recited in claims 2 and 9. See below for reasons.

Group VI, claim(s) 13-16, 19-21, and 23-26, drawn to a method for diagnosis, prophylaxis, therapy, follow-up and/or aftercare of diseases comprising using an antisense polynucleotide of group I.

Group VII, claim(s) 13-16, 19-21, and 23-26, drawn to a method for diagnosis, prophylaxis, therapy, follow-up and/or aftercare of diseases comprising using a DNAzyme of group II.

Group VIII, claim(s) 13-16, 19-21, and 23-26, drawn to a method for diagnosis, prophylaxis, therapy, follow-up and/or aftercare of diseases comprising using a peptide nucleic acid of group III.

Group IX, claim(s) 13-16, 19-21, and 23-26, drawn to a method for diagnosis, prophylaxis, therapy, follow-up and/or aftercare of diseases comprising using a ribozyme of group IV.

Group X, claim(s) 13-16, 19-21, and 23-26, drawn to a method for diagnosis, prophylaxis, therapy, follow-up and/or aftercare of diseases comprising using an siRNA of group V.

Group XI, claim(s) 27, drawn to a method for inhibiting cell proliferation rate and inducing cell apoptosis comprising using an antisense polynucleotide of group I.

Group XII, claim(s) 27, drawn to a method for inhibiting cell proliferation rate and inducing cell apoptosis comprising using a DNAzyme of group II.

Group XIII, claim(s) 27, drawn to a method for inhibiting cell proliferation rate and inducing cell apoptosis comprising using a peptide nucleic acid of group III.

Group IVX, claim(s) 27, drawn to a method for inhibiting cell proliferation rate and inducing cell apoptosis comprising using a ribozyme of group IV.

Group XV, claim(s) 27, drawn to a method for inhibiting cell proliferation rate and inducing cell apoptosis comprising using an siRNA of group V.

The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of groups I-XV are found to have no special technical feature that define a contribution over the prior art of Cech et al. (US 6,444,650 B1, 2002). The reference of Cech et al., teach antisense oligonucleotides directed against the catalytic protein component of human telomerase, specifically targeting Gene accession number AF015950 (Figure 1 and SEQ ID NO:1). Therefore, applicants' invention of the polynucleotide directed towards a gene of a catalytic subunit of human telomerase does not contribute a special technical feature when viewed over the prior art. Accordingly, the claimed inventions do not have a single inventive concept and so lack unity of invention, thus restriction for examination purposes as indicated is proper.

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed polynucleotide target sequence regions, the Marksuh group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity and

(B)(1) a common structure is present, i.e, a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant polynucleotide target sequence regions are considered to be each separate invention for the following reasons:

As described above, the polynucleotide target sequence regions do not meet the criteria of (A), common property or activity or (B)(1), common structure or (B)(2), art recognized class of compounds. Although all polynucleotide target sequence regions are in accordance with Gene Accession number AF015950, each sequence region behaves in a different way in the context of the claimed invention because each region comprises different nucleic acid sequences that constitute a particular regions of an mRNA. Therefore, each sequence region cannot be substituted one for the other, with the expectation that the same intended result would be achieved. Further, although the polynucleotide target sequence regions disclosed in the claims may interact with the mRNA of the catalytic subunit of human telomerase, the sequence regions do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the sequence regions is lacking and each agent claimed is considered to constitute a special technical feature. Therefore, applicants are required to elect two target sequence regions as indicated above.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Inventorship

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana Shin
Examiner
Art Unit 1635

D. Shin
5-1-2006

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER